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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,157	08/22/2005	Thomas Schulz	18465-0036	4132

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EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,157	SCHULZ ET AL.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15,18-20,24,26-36,38-40,42 and 44-53* is/are pending in the application.

4a) Of the above claim(s) *1-12,15,18-20,24,27-36,38,39 and 46-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26, 40, 42, 44, 45, 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 26, 36, 38-40, 42, and 44-53, and species election drawn to GABAnergic neurons are acknowledged. The traversal is on the ground(s) that the examination of each of the groups and species can be made without serious burden. This is not found persuasive because the inventions are distinct as indicated on record, a neural cell could be produced with different methods, and used in materially different process; and claims to the different species recite mutually exclusive characteristics of each species, such as different types of neurons and neuronal markers. These species are not obvious variants of each other based on the current record. There is an examination and search burden for these patentably distinct inventions and species due to their mutually exclusive characteristics. Each of the inventions and species requires a different field of search (e.g., searching different classifications, employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

As such, the searches for different groups and species would have certain overlap, but they are not co-extensive. M.P.E.P. states, "FOR PURPOSES OF THE INITIAL REQUIREMENT, A SERIOUS BURDEN ON THE EXAMINER MAY BE PRIMA FACIE SHOWN IF THE EXAMINER SHOWS BY APPROPRIATE EXPLANATION OF SEPARATE CLASSIFICATION, OR

SEPARATE STATUS IN THE ART, OR A DIFFERENT FIELD OF SEARCH AS DEFINED IN MPEP § 808.02". Therefore, it is maintained that these inventions are distinct due to their divergent subject matter. Further search of these inventions is not co-extensive, as indicated by the separate classifications. The requirement is still deemed proper and is therefore made **FINAL**.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 1-12, 15, 18-20, 24, 26-36, 38-40, 42, 44-53 are pending, however, claims 1-12, 15, 18-20, 24, 27-36, 38-39, 46-52 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 26, 40, 42, 44, 45, 53 are under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 42, 44, 45, 53 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims fail to correspond in scope with that which

applicant(s) regard as the invention can be found in the specification, where the applicant has stated "The neural **progenitor** cells are characterized by the expression of nestin or vimentin" (Specification, paragraph 0023, emphasis), while claim 40 states, "neural cells derived in vitro from pluripotent cells ...express one or more detectable markers for nestin or vimentin" and "the neural cells have the capacity to differentiate into cells of a neural lineage". This discrepancy indicates that which cell type (i.e. differentiated neurons or neural progenitor cells) the markers belong to as described in the specification is different from what is defined in the claim(s).

In light of the state of the art, it appears claim 40 states the property of a neural progenitor cell in terms of markers expressed and the cell differentiation capability, yet claim is drawn to a differentiated neural cell. Appropriate clarification is required.

While the claim may be amended, applicant is reminded that the elected invention currently under examination is a neural cell, not a neural progenitor cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 40, 42, 44, 45, 53 are rejected under 35 U.S.C. 102(a) as being anticipated by *Carpenter et al* (Exp Neurol 2001;172;383-97, IDS).

Carpenter et al teach a cell culture composition comprising a population of human cells, expressing nestin (e.g. fig. 2B), and differentiated into cells of a neural lineage, preferably a GABAergic neuron phenotype (e.g. fig. 3C). The culture disclosed by *Carpenter et al* comprises both GABA neurons and nextin-expressing nueral progenitors. Accordingly, *Carpenter et al* anticipate instant claims.

It is noted in this and following rejections, the prior art neural cell differs from the claimed neural cell only by their method of manufacture. However, patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims, and a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

Claims 40, 42, 44, 45, 53 are rejected under 35 U.S.C. 102(b) as being anticipated by *Deng et al* (Biochem Biophy Res Comm 2001;282:148-52).

Deng et al teach a cell culture composition comprising undifferentiated cultures of human marrow stromal cells (hMSCs), expressing vimentin (e.g. the abstract). Under certain treatment, about 25% of the hMSCs differentiated into cells with a typical neural cell morphology (e.g. figs. 1, 3, table 1), and thus have the capability to differentiate into cells of a neural lineage. Accordingly, *Deng et al* anticipate instant claims.

Claim 26 is rejected under 35 U.S.C. 102(a) as being anticipated by *Jain et al* (Exp Neurol 2003;182:113-23).

Jain et al teach a population of neural cells, about 15-60% are immunopositive for GABAergic marker (e.g. fig. 2B, 2D). Accordingly, *Jain et al* anticipate instant claims.

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by *Westmoreland et al* (Biochem Biophy Res Comm 2001;284:674-80).

Westmoreland et al teach a population of neural cells differentiated from mouse embryonic stem cells express mRNAs characteristic of GABAergic neurons, i.e. positive for the glutamate decarboxylase genes and the vesicular inhibitory amino acid transporter gene (e.g. the abstract, and figs. 1-2). Accordingly, *Westmoreland et al* anticipate instant claims.

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by *Benagiano et al* (Histochem Cell Biol 2000;114:191-5).

Benagiano et al teach a neural cell in postmortem human cerbellar cortex characteristic of GABAergic neurons, i.e. immune positive for the glutamate decarboxylase (e.g. figure). Accordingly, *Benagiano et al* anticipate instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 40, 42, 44, 45, 53 aare provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 46-52 of copending Application No. 10/539,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both drawn to a neural cell.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history

information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
June 25, 2007